Document Coversheet

Study Title: Human Perception of Odors and Odor Blockers

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	2/5/2025
NCT Number:	NCT06191419
IRB Number	43123
Coversheet created:	7/2/2025

KEY INFORMATION FOR: HUMAN PERCEPTION OF ODORS AND ODOR BLOCKERS

We are asking you to choose whether or not to volunteer for a research study about the effect of odors on motivation to perform smoking-related behaviors. We are asking you because you are a smoker, 18 – 60 yrs of age, with normal senses of smell and taste. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn about the perception of pleasantness of certain odors - and especially how mixing odors alters smell perception and motivation to perform activities related to smoking. Your participation in this research will last about 1 - 2 hrs per session and can include multiple (up to 4) sessions.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

To help us understand the perception of odors and ways to modify the effects of on behavior and perception. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Allergic reactions (fragrance allergies), negative emotional reactions, and odor-induced feelings of nausea are rare, but do occur. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Tim McClintock, Ph.D. of the University of Kentucky, Department of Physiology at mcclint@uky.edu or 859-323-1083.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You should not participate in this study if you are not a smoker, if you are pregnant, if you have a neurological condition, if you experience migraine headaches, if you have a significant deficiency in your ability to smell or taste, if you have ever suffered from fragrance allergy, or if you currently have a head cold or are suffering from an allergy.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at the UK Medical Center. You will need to come 1 - 4 times during the study depending on whether you volunteer to test multiple sets of odors. Each of those visits will take about 1 – 2 hours. The total amount of time you will be asked to volunteer for this study can range from 1 – 8 hours over the next 3 months.

WHAT WILL YOU BE ASKED TO DO?

You will be seated at a table near fume hood or odor capture device used to prevent odors from accumulating in the room. A researcher will instruct you on how to sniff an odor sample and how to rate parameters of odor samples. Once you are comfortable with the procedures for sniffing samples and rating them, the researcher will give you the first odor sample. Once you have scored this sample and returned it to the researcher, the researcher will wait 2 - 3 minutes before giving you the next sample. This waiting period prevents your olfactory system from desensitizing or becoming fatigued. During the session you are allowed to take a break and leave the room to attend to personal concerns such as making a phone call or using the bathroom, but no smoking is allowed during breaks and please try to avoid encountering any strong odors or flavors. In other words, it is best not to eat or drink anything besides water during the break.

There are no wrong ratings. We are simply interested in knowing how you feel about these odors and their effect on your motivational state.

The odor samples are presented in a random order, meaning the order is determined by chance. This order is different for every subject, so each odor has the same chance of being first, last, or in the middle across all participants. Ordering the samples differently for each participant controls for people's tendency to change how they rate things as they work through a list of items.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- Experiencing a negative physical reaction to simply smelling an odor is rare. However, it is possible that you may have an undiagnosed sensitivity to an odor. Known negative physical reactions include odor-triggered migraine headaches and allergic reactions called fragrance allergies. Odors may also trigger nausea, and encountering an odor that is linked to an event in your past can trigger memories with strong emotional content.
- If you have a negative physical reaction, including nausea, please inform the researcher and the testing will be aborted immediately in order to protect you.
- If you have an emotional reaction during the testing, please inform the researcher. The researcher will counsel you to take a short break and even abort the testing if the response is a negative emotion. However, you may choose to resume the testing as long as no other symptoms arise.

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Headaches, including migraines	Rare in people with no past migraine history	Usually of short duration	Yes, speak with your physician
Fragrance allergy	Rare in people with no past history	Onset usually is rapid. Sneezing or watery eyes are not serious problems; breathing	Usually resolves in minutes or a few hours; but see physician immediately if

		difficulties or skin hives are serious and need attention.	breathing difficulty or hives develop.
Nausea	Rare, less so in pregnant women	Will not impact your overall health.	No, other than avoiding the odor trigger
Emotional response to an odor-triggered memory	Encounters with odors that trigger emotional memories are unlikely in this study.	Will not impact your overall health.	No, other than avoiding the odor trigger

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs to participate.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Information identifying you as taking part in the study is stored in a safe in a locked room. The information collected from you during the study does not contain identifying information and is stored only in a password-protected computer kept in a locked room, and on a secure university server as back-up.

You should know that in some cases we may have to show your information to other people because of legal requirements. For example, the law may require or permit us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, such as child or adult protective services, if you report information about a child or elder being abused;
- authorities or a mental health professional if you pose a danger to yourself or someone else (e.g. suicidal thoughts).

To ensure the study Is conducted properly, officials of the University of Kentucky and the National Institutes of Health may look at or copy pertinent portions of records that identify you.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,

- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator know if you are in another research study. You should discuss this with the investigator before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Tim McClintock at 859-940-3364 immediately. Dr. McClintock will refer you to the appropriate health care experts, or recommend that you call 911. They will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm:

- will be your responsibility; or
- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); or
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive $30 per testing session in the form of a check for taking part in this study.

With a few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will not provide you with individual research results.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to 10 times per year.

Do you give your permission to be contacted in the future by Dr. McClintock regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 40 people to do so at the University of Kentucky.

The University of Kentucky College of Medicine and the National Institutes of Health is providing financial support and/or material for this study.

The information that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____ **Signature of research subject**	_____ **Date**
_____ **Printed name of research subject**	
_____ Printed name of [authorized] person obtaining informed consent	_____ Date